REMARKS

I. Status of the Claims

Claims 1 and 3 through 13 are pending in the application. Claim 1 is the sole independent claim and the subject matter of claim 2 has been incorporated into Claim 1, as suggested in the Office Action. No new matter has been added. Reconsideration of the outstanding rejections is requested in view of the foregoing amendment and these remarks.

II. Summary of the Amendment

As amended, the claims are more closely directed to the treatment of individuals having increased bone turnover with ospemifene.

III. Rejections Under 35 U.S.C. § 112

The structure of Formula (I) has been incorporated into independent claim 1, which is believed to overcome the 35 U.S.C. § 112, first paragraph rejection.

To the extent that the remarks in the Office Action pertain to the amended claims, Applicants submit that active pharmaceutical compounds are routinely formulated as salts, and that pharmaceutical compound claims are routinely allowed with a scope that includes the pharmaceutically acceptable salts of a compound. "Pharmaceutically acceptable salts" are known in the art, and described for example, in WO 96/07402 and WO 97/32754, which are background information, incorporated by reference in the specification. *See* page 1, paragraph [0002] and page 3, paragraph [0007] of the specification. Accordingly, it is respectfully requested that the Section 112 rejection be withdrawn, because numerous examples of "pharmaceutically acceptable salts" are incorporated by reference into the specification, and it is clear that one of ordinary skill in

the art would understand the scope and meaning of that phrase. Thus, it should be permitted in amended claim 1.

The "metabolites" of the compound of formula (I) has been limited to the handful of known metabolites disclosed in the specification at page 5, paragraph [0018], which is believed to overcome the 35 U.S.C. § 112, first paragraph rejection on that score.

As amended claim 1 contains a chemical formula, there should be no question that one of ordinary skill in the art can determine the geometric isomers and stereoisomers thereof. Accordingly the 35 U.S.C. § 112 rejection should be withdrawn insofar as it relates to those terms.

Applicants disagree with the analysis with respect to "esters" of the compound of Formula I, but the claim language reciting "esters" has been removed from the amended claim to expedite prosecution.

Applicants respectfully traverse the alleged "New Matter Rejection" at pages 5-6 of the application, and do not understand the basis for the rejection. As amended, claim 1 recites measuring a bone loss marker or a bone formation marker. The measurement of these markers is clearly described at paragraphs [0019]-[0023] and in original claims 6-11, and in fact, throughout the specification. As set forth in the specification at paragraph [0019], "increased bone turnover" means high bone resportion and bone formation, and these values are obtained by measuring the markers. In other words, high bone resorption and formation are measured by the values of certain markers in the target population, compared to the values that the markers have in a "normal" population. To some extent, it appears the Office Action objects to the word identified – and if that is the case, this is a formal objection and should be withdrawn. To say that high bone turnover means high bone resorption and formation with respect to a norm (as it says in the specification) is the same as saying that high bone resorption and formation identify high bone turnover. If this issue remains after reconsideration, applicants suggest that it

might be resolved (and if necessary, alternative language selected) in a telephone interview with the Examiner.

The claim limitation "effective to decrease bone loss" is amply supported in the experimental section. *See* Tables 2 and 3 and the associated paragraphs at pages 8 and 9. Reconsideration is respectfully requested.

IV. Double Patenting

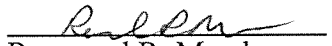
Claim 1 was provisionally rejected for alleged obviousness-type double patenting in view of claims 1 through 9 of co-pending Application No. 11/183,185 (Office Action, pages 6-7). The foregoing amendment, limiting the scope of present claim 1 to compounds according to Formula (I), its salts, etc., is believed to overcome this rejection. Applicants also note that said Application No 11/183,185 has a later filing date, and the patent, when issued, will have a later expiration date than any patent issuing from the present application. Accordingly, there appears to be no possibility of a "timewise extension" of the right to exclude based on the present claims, said to be the basis for the rejection.

CONCLUSION

The amended claims are believed to be allowable for the foregoing reasons. Applicants respectfully request reconsideration of the outstanding rejections and objections.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our address given below.

Respectfully submitted,



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